No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY TO BRIEF IN OPPOSITION

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November 13, 2012

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INTRODUCTION

The First Circuit recognized that it created a "split in the lower courts" and practically begged this Court to provide "a decisive answer" on this "question of exceptional importance." App. 10a-11a. Respondent now tries to obscure that conflict by pretending that the stop-selling theory is good for one claim and one state only. She is wrong. The Fifth Circuit recently rejected this same theory of design-defect liability *for the second time*, just like the Sixth and Eighth Circuits rejected identical stop-selling arguments before it.

Indeed, this case demonstrates in spades that there is no plausible basis for distinguishing design-defect claims from failure-to-warn claims for purposes of the stop-selling theory. Consistent with comment k, the instructions in this case make clear that the jury's verdict hinged on precisely what *Mensing* barred: a finding that petitioner's FDA-mandated warnings were inadequate. More broadly, the First Circuit conceded that Hatch-Waxman's sameness mandate applies equally to design-defect and failure-to-warn claims, App. 10a, *and* that the stop-selling theory could be deployed equally against both claims. App. 11a. Given the record and those concessions, the stop-selling theory can be right only if *Mensing* is wrong—which is why the First Circuit effectively challenged this Court to reconsider that decision. *Id*.

That is not how our legal system works. The First Circuit may not like *Mensing*, but it had no business defying this Court and daring it to say that *Mensing* meant what it said. This Court should grant the petition and summarily reverse.

ARGUMENT

A. The First Circuit Erred By Creating A Circuit Split.

Respondent argues "[t]here is no circuit conflict" because this case "is the first … and only" post-*Mensing* decision addressing "theories other than failure to warn." BIO 7. That is demonstrably false, as the First Circuit conceded, App. 11a, and the Fifth Circuit's post-remand decisions in *Demahy* underscore.

Demahy involved myriad claims against generic manufacturer Actavis, including for design defect. Pet. 11. And respondent now acknowledges that the Fifth Circuit considered *Mensing*'s scope on remand and rejected that lawsuit *in its entirety*: It "remanded for entry of judgment in favor of [Actavis]," including on design defect. BIO 11 (citing *Demahy v. Actavis, Inc. [Demahy I]*, 650 F.3d 1045 (5th Cir. 2011)).

Demahy's most telling feature, however, is not what respondent acknowledges; it is what she fails to disclose. After the district court entered judgment for Actavis, Demahy appealed—asserting (like respondent, BIO 10-11) that the original *Demahy* appeal involved only failure-to-warn claims, and that the district court therefore misconstrued the mandate as foreclosing design-defect liability. Indeed, citing this decision, Demahy argued that her stop-selling theory of design-defect liability survived *Mensing*. Notice of Supp. Auth., *Demahy v. Schwarz Pharma, Inc. [Demahy II]*, No. 11-31073, at 2 (5th Cir. filed May 3, 2012) ("*Bartlett* … determined that since Mutual could decide not to manufacture an unreasonably dangerous drug, [federal law] would

permit the states to impose liability for continuing to sell [it].").

The Fifth Circuit decisively rejected those claims before respondent filed her BIO. *Demahy II*, 2012 WL 5261492 (Oct. 25, 2012). It explained that the prior *Demahy* courts considered design-defect and failure-to-warn claims materially indistinguishable, and therefore affirmed the trial court's conclusion that *Demahy I* rejected her design-defect claim pursuant to *Mensing*. *Id.* *5. It then held in the alternative that federal law preempts the stop-selling theory anyway:

> Post-*Mensing* … courts have specifically held … that state-law tort claims against generic drug manufacturers, including design defect claims, are preempted after *Mensing*. Thus, although unnecessary for the disposition [given our alternative holding regarding *Demahy I*], we are persuaded that Demahy's design defect claim would be preempted.

Id. *6 (citations and footnotes omitted).

These events fatally undermine respondent's rejection of the First Circuit's admission that there is a "split in the lower courts [which] needs a decisive answer." App. 11a. The Fifth Circuit has rejected respondent's stop-selling theory *twice*. And it is not alone. The Sixth and Eighth Circuits likewise have rejected it. Pet. 1-2, 19-21 *(*discussing *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011); *Mensing v. Wyeth*, 658 F.3d 867 (8th Cir. 2011)).

Respondent downplays those decisions by claiming they rejected this theory only for failure-to-

warn claims. BIO 9-11. That is no distinction, as the First Circuit acknowledged by conceding that Hatch-Waxman's sameness mandate applies equally to generic design. App. 10a ("[Petitioner] cannot legally make sulindac in another composition."); *see also Mensing*, 131 S. Ct. at 2574 n.2 (explaining that generic drugs must be "identical in active ingredients, safety, and efficacy"). Yet apart from declaring that *Wyeth* created a "general no-preemption rule" that might lead this Court to reconsider the stop-selling theory "despite what [it] made of similar arguments in [*Mensing*]," App. 10a-11a—a suggestion even respondent refuses to defend—the court did not even try to explain why federal law would preempt respondent's stop-selling theory in the warnings context but not the design context. Indeed, it admitted there is no such explanation. *Id.* ("[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug.").

Respondent nonetheless seeks to reconcile these decisions by asserting that failure-to-warn claims are based on a duty *to change* product warnings (conduct federal law bars), whereas design-defect claims are based on a duty *to stop selling* the product (conduct federal law permits). BIO 25-26. That is just wordplay. Saying that failure-to-warn liability is imposed because a manufacturer *failed to change* the warning is just the flipside of saying that liability is imposed because the manufacturer *sold a product with a defective warning*. The manufacturer's duty is "to adequately and safely label [its] products" for sale, *Mensing*, 131 S. Ct. at 2577, so it has two options: Change the label or stop selling it.

That is just like respondent's design-defect claim, which asserted petitioner *sold a product with a defective design*. State law offered the same two options: Change the design or stop selling it. And because Hatch-Waxman equally precludes labeling *and* design changes, state law *in both cases* seeks equally to impose liability for selling products that manufacturers cannot lawfully "fix."

Mensing's rejection of the stop-selling theory thus cannot be limited to failure-to-warn claims. Indeed, its logic extends *to every claim*, because every products case begins *with a sale*. Without one, there is no basis to sue—and no need for a preemption defense. But because plaintiffs can *always* argue that defendants were permitted to stop selling their products, the stop-selling rationale would prevent defendants from *ever* asserting conflict preemption successfully. *In re Darvocet*, MDL No. 2226, 2012 WL 718618, *3 (E.D. Ky. Mar. 5, 2012) (rejecting stop-selling theory because it "could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct"); *see also Mensing*, 131 S. Ct. at 2579 ("We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless.").

Were this theory viable, *Mensing* thus would have *rejected* preemption; as the First Circuit conceded, generic manufacturers can avoid failure-to-warn *and* design-defect liability by suspending sales. App. 11a. Respondent nonetheless seeks to cabin the stop-selling rationale to design-defect cases by claiming that it is "an indirect means" of complying with state

labeling duties, but a direct means of complying with state design requirements. BIO 26; *id.* 27. That hinges on the same fiction addressed earlier—that the underlying state-law duties are structurally distinct (they are not). But the argument fails even on its terms. Federal law's preemptive force does not turn on whether the stop-selling end-run is "direct" or "indirect." If the Supremacy Clause means anything, it means states cannot require companies *to violate federal law as a precondition to doing business within their borders*. That is why the other circuits and scores of district courts have rejected the stop-selling theory.[1]

It also is why this Court long ago rejected the "choice-of-reaction" thesis, which held that federal law does not preempt state tort claims because defendants can *both* sell their products *and* pay damages. Pet. 28-31 (explaining the conflict with *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). Respondent says these cases are irrelevant because they presume "the defendant will continue to violate state law [by selling products], thus the need to continue to pay damages." BIO 28 (quotation omitted). But that is the point: These cases held that state tort law cannot effectively require companies to violate federal law if they want to sell their products

[1] Respondent distinguishes the district court cases *on state-law grounds*, asserting that several arose in jurisdictions requiring proof of a feasible alternative design. BIO 17-18. Whatever merit that independent state-law defense may have had, these decisions considered and rejected the stop-selling theory under *Mensing*. *See* Pet. 19-21.

free from liability. *Cipollone*, 505 U.S. at 521 (quotation omitted); *see also Riegel*, 552 U.S. at 324.[2]

At bottom, the First Circuit rightly acknowledged that it had created a "split in the lower courts." App. 11a. Its decision conflicts *both* with the Fifth, Sixth, and Eighth Circuits' recognition that *Mensing* forecloses the stop-selling theory, *and* with the line of cases culminating in *Cipollone* and *Riegel*.

B. The First Circuit's Decision Warrants Review And Summary Reversal.

The First Circuit's outlier decision undeniably warrants review. The appellate court recognized this case presents "a question of exceptional importance," App. 8a, and specifically called for "a decisive answer from [this Court]." App. 11a. Respondent's lawyers agreed. They hailed the decision as "potentially huge" because it "establishes that *Mensing* … has no relation to a product defect case." S. Hsieh, *First Circuit Gives Plaintiffs' Lawyers Opening In Drug Suits*, NEW ENGLAND IN-HOUSE (June 30, 2012), http://newenglandinhouse.com/2012/07/13/1st-circuit-gives-plaintiffs-lawyers-opening-in-drug-suits/ (visited Nov. 12, 2012). And they candidly admitted the decision sows "fertile ground for an appeal." T. Buckland, *Plaistow Woman's Lawsuit Could End Up*

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[2] It is irrelevant that *Cipollone* and *Riegel* involved express-preemption clauses. BIO 28 n.23. Those provisions preempted state-law requirements *that conflicted with federal law*, and the cases held that conflict could not be avoided by conditioning product sales on paying damages. *Riegel*, 552 U.S. at 323-24 (describing cases).

Before Supreme Court, N.H. UNION LEADER (May 9, 2012).

Respondent now runs from those concessions—asserting that design-defect claims are so "difficult to prove," BIO 12, and New Hampshire law so exotic, BIO 12-13, 29-32, that the question presented will "not recur with sufficient frequency to warrant … review." BIO 14. Not so.

As petitioner explained (Pet. 23-25), the First Circuit held (App. 7a), and respondent concedes (BIO 4), New Hampshire has adopted comment k—like most other states, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1077 n.41 (2011). That eliminates any distinction between failure-to-warn and design-defect claims for preemption purposes, because comment k precludes design-defect liability so long as pharmaceutical products are "'accompanied by proper directions and warning.'" BIO 4 (quoting *Restatement (Second) of Torts* § 402A, cmt. k). New Hampshire design-defect liability thus hinges on challenging the adequacy of product warnings, as it does virtually everywhere else.

The jury instructions illustrate this point:

> If you determine that Sulindac was unreasonably dangerous *and that a warning was not present and effective to avoid that unreasonable danger*, then you must find [respondent] has proven this element of her claim, a defect in design. However, if you determine that sulindac was unreasonably dangerous, *but that a warning was present and effective to avoid that unreasonable danger*, then you must find for [petitioner].

Supp. App. 3a (emphases added). Accordingly, there is no question the the jury's verdict depended on its finding petitioner's FDA-mandated warnings inadequate.

That not only forecloses respondent's claim that this case turned on a quirk of New Hampshire law; it exposes just how dramatically the First Circuit deviated from *Mensing*. *Mensing*'s whole point is that Hatch-Waxman's sameness mandate immunizes a generic product's FDA-mandated warnings from attack because it prohibits generic manufacturers from altering them. 131 S. Ct. at 2577. That *rationale* applies *a fortiori* to claims challenging FDA-mandated generic product design, as the appellate court conceded. App. 10a. The key point here, however, is that the court's decision eviscerates *Mensing*'s *holding*, by allowing precisely what *Mensing* forbids. In short, the jury's $21 million verdict depended on the very thing *Mensing* said it could not.

That cannot be right. And if the stop-selling evasion lets plaintiffs challenge FDA-mandated warnings in defective-design cases, there is no principled reason why plaintiffs could not do so in defective-warnings cases. It would be like *Mensing* never happened; we would be back to the Eighth Circuit's pre-*Mensing* declaration that generic manufacturers are liable because they "were not compelled to market metoclopramide. If they realized their label was insufficient … they could have simply stopped selling [it]." *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009). The First Circuit might prefer that approach, but *Mensing* bound the court to reject it.

Respondent offers two answers. She first claims petitioner waived this comment k *argument* by withdrawing its comment k *defense*. BIO 14, 19-20, 31-32. Nonsense. As respondent concedes (BIO 14), petitioner repeatedly argued that comment k eliminated any difference between failure-to-warn and design-defect claims for preemption purposes. *E.g.*, Pet'r's Mem. In Supp. Of Summ. J., 2010 WL 1371985, at 31 (Mar. 30, 2010) ("[D]rugs are unavoidably unsafe products, and as such, cannot be defective in design as long as they are accompanied by adequate warnings. As such, any design claim directly implicates warnings and thus, falls under the same preemption analysis.") (citation omitted).

Nothing obligated petitioner to present this legal argument to the jury; the argument's whole point is that comment k *should have prevented this case from reaching the jury* because *Mensing* precludes challenges to generic warnings. It was enough to raise this argument at summary judgment. *City of St. Louis v. Praprotnik*, 485 U.S. 112, 120 (1988). And waiver applies to legal *claims*—not legal *arguments*—anyway. *Yee v. City of Escondido*, 503 U.S. 519, 534-35 (1992).[3]

In any event, the withdrawal of petitioner's comment k defense did not remotely dissuade

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[3] Nor is this a vehicle issue, BIO 20 (claiming review should await a case where "the drug manufacturer has presented a [comment k] defense"). If anything, the withdrawal of this fact-dependent defense makes this an ideal vehicle, because it puts the purely legal question in sharpest relief (like *Mensing*, which was decided at the 12(b)(6) stage).

respondent from mounting the very attacks *Mensing* bars. Indeed, it is astonishing that she now denies challenging the adequacy of petitioner's FDA-mandated warnings at trial (BIO 31). She did so repeatedly:

> Mr. Jensen: [H]ave you assessed whether [petitioner's] label … has an effective or adequate warning for SJS/TEN?
>
> Dr. Tackett: I do not think it does have an adequate warning or effective warning.

Supp. App. 6a-7a.

> Mr. Jensen: The fact that [FDA later changed the label], what if any bearing does that have on your opinion about the effectiveness or lack thereof of the prior Sulindac label?
>
> Dr. Tackett: Well, it definitely indicates the label was inadequate.

Supp. App. 9a.

> Mr. Jensen: What, if any, opinion have you reached as to whether or not [petitioner's] label had an effective warning for SJS and TEN?
>
> Dr. Tackett: As I've said before, I do not think it was effective. The new label basically has a better warning.

Supp. App. 12a.

Given this record, respondent ultimately asserts this case is *sui generis* because it is hard to convince juries *both* that the warnings are inadequate *and* that the product's risks outweigh its benefits. BIO 12-13 & n.11. Respondent's immodest

suggestion that only her lawyers can whip jurors into a frenzy is baseless. As *Riegel* observed, juries are notoriously ill-equipped to second-guess FDA's expert risk-benefit analysis because they "see[] only the cost of a more dangerous design, and [are] not concerned with its benefits; the patients who reaped those benefits are not represented in court." 552 U.S. at 325.

That is why thousands of plaintiffs continue to pursue generic design-defect claims undaunted by the hurdles respondent alleges. *E.g.*, *In re Darvocet*, 2012 WL 718618 (federal MDL); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012) (same); *In re Fosamax*, MDL No. 2243, 2011 WL 5903623 (D.N.J. Nov. 21, 2011) (same). And emboldened by this outlier decision, new claims are being filed weekly.

Ultimately, it is hard to overstate how important it is for this Court to make clear that *Mensing* meant what it said. This verdict was the largest in New Hampshire history, and as the *amici* briefs explain, the First Circuit's demand that generics either withdraw their products or face ruinous liability jeopardizes both the industry and the federal scheme. Br. for Morton Grove 10-11, 16. Indeed, it is hard to conceive a result more at odds with Hatch-Waxman. The statute's whole purpose was to lower healthcare costs by making generic drugs widely available; in *Mensing*'s words, "it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." 131 S. Ct. at 2582; App. 10a ("There is no doubt that Congress wanted to reduce medical costs by spurring

generic copycat drugs [and *Mensing*] held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required.").[4]

Given its frontal assault on Hatch-Waxman's core objectives, the First Circuit rightly acknowledged this case presents "a question of exceptional importance," App. 8a, and asked this Court to provide "a decisive answer." App. 11a. That is the one part of its decision everyone should agree on, and we respectfully submit that this Court should heed its request.

CONCLUSION

This Court should grant the petition and summarily reverse.

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[4] Respondent's claim that petitioner waived its argument regarding Hatch-Waxman's objectives (BIO 21; *id.* 28 n.22) is frivolous. The Petition made this very point, Pet. 31-32, and the Court otherwise can consider any issue "fairly included" in the question presented. Rule 14(1)(a).

November 13, 2012

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

08-CV-358-JL
September 2, 2010; 8:45 A.M.

KAREN L. BARTLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

TRANSCRIPT OF JURY TRIAL
MORNING SESSION
BEFORE THE HONORABLE JOSEPH N. LAPLANTE

APPEARANCES:

For The Plaintiff:

Keith M. Jensen, Esq., Eric N. Roberson, Esq., Xavier A. Gonzalez, Esq. Bryan Ballew, Esq., Jensen Ballew & Gonzalez, PLLC

For the Defendant:

Joseph P. Thomas, Esq., Paul J. Cosgrove, Ulmer & Berne LLP,

Stephen J. Judge, Esq., Pierre A. Chabot, Esq. Wadleigh, Starr & Peters, PLLC

Court Reporter:

Susan M. Bateman, LCR, CM, CRR, Official Court Reporter, U.S. District Court, 55 Pleasant Street, Concord, NH 03301, (603) 225-1453

* * *

Mrs. Bartlett must prove, first, that Mutual was in the business of selling Sulindac. It is not necessary for Mrs. Bartlett to prove that Mutual sold Sulindac directly to her or directly to the pharmacy that filled her prescription. It is sufficient if Mrs. Bartlett proves that Mutual placed Sulindac into the stream of commerce.

A defect in design occurs when the product has been manufactured in conformity with the manufacturer's design but the design itself presents unreasonable danger to consumers.

In deciding whether Sulindac's design presented unreasonable danger, you should consider the usefulness and desirability of the product to the public as a whole. A product is defective as designed if the magnitude of the danger outweighs the utility or usefulness of the product.

You should also consider whether Sulindac's risk of danger, if any, could have been reduced without significant impact on the product's effectiveness or its manufacturing cost. Liability may exist if the manufacturer did not take available and reasonable steps to lessen or eliminate the danger of even a useful and desirable product.

Bear in mind that a manufacturer is not obliged to design the safest possible product, or a safer product, or one as safe as others make, so long as the design it has adopted is not unreasonably dangerous.

By the same token, you may find that a product's design was unreasonably dangerous even if the plaintiff has not presented evidence of an alternative design that could have made the product safer.

Now, if you determine that Sulindac was unreasonably dangerous, you may consider the presence and efficacy or effectiveness of a warning to avoid an unreasonable risk of danger from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous even with its warning.

If you determine that Sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger, then you must find Mrs. Bartlett has proven this element of her claim, a defect in design. However, if you determine that Sulindac was unreasonably dangerous, but that a warning was present and effective to avoid that unreasonable danger, then you must find for Mutual.

A manufacturer is not responsible for injuries caused by a product's defective condition unless the purpose and manner of the plaintiff's use of the product were reasonably foreseeable by the manufacturer. In terms of foreseeability, we are talking about reasonable foreseeability and not some sort of prophetic vision as to what might conceivably happen. A manufacturer may be held liable even if the user employs the product in an unintended but foreseeable manner.

A product's defective condition is a legal cause of the plaintiff's injuries if it directly and in natural and continuous sequence produces or substantially contributes to producing the injuries, so that it can reasonably be said that but for the defective condition the injuries would not have occurred.

In determining whether the defective condition was a legal cause of the plaintiff's injuries, you need

not find that the defective condition was the sole cause of the injuries, but only that it was a substantial factor in bringing about the injuries, even though other factors may have contributed to the cause of the injuries.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

08-CV-358-JL
August 20, 2010; 1:00 P.M.

KAREN L. BARTLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

DAY 5
TRANSCRIPT OF TRIAL
AFTERNOON SESSION
BEFORE THE HONORABLE JOSEPH N. LAPLANTE
AND A JURY

APPEARANCES:

For The Plaintiff:

Keith M. Jensen, Esq., Eric N. Roberson, Esq., Xavier A. Gonzalez, Esq. Bryan Ballew, Esq., Jensen Ballew & Gonzalez, PLLC

For the Defendant:

Joseph P. Thomas, Esq., Paul J. Cosgrove, Ulmer & Berne LLP,

Stephen J. Judge, Esq., Pierre A. Chabot, Esq. Wadleigh, Starr & Peters, PLLC

Court Reporter:

Sandra L. Bailey, LCR, CM, CRR, Official Court Reporter, U.S. District Court, 55 Pleasant Street, Concord, NH 03301, (603) 225-1454

* * *

MR. JENSEN: Exhibit 48B, Sulindac label. Permission to publish.

THE COURT: The Sulindac label? So it's a full exhibit?

MR. JENSEN: I gather.

THE COURT: Okay. Of course you can publish it.

Q. By MR. JENSEN: Where is—strike that. Is—

THE COURT: It's a full exhibit?

THE CLERK: Yes, your Honor.

THE COURT: The identification is not stricken from that but, okay, proceed.

Q. Is SJS and TEN mentioned in the Sulindac label?

A. It is.

Q. Approximately what paragraph do we need to read to before we can see it?

A. It's pretty far down there. If you were to number them, it's probably around paragraph 64.

Q. Okay. And is this label the one, the one that was, it says revised February 2002. Do you see that, sir?

A. Yes, I do.

Q. And was this or was this not the label that was in effect in December of 2004 when Karen Bartlett was prescribed this drug?

A. It would be the label that would be in effect.

Q. Okay. And have you assessed whether or not this label to start with has an effective or adequate warning from SJS/TEN?

A. I do not think it does have an adequate warning or effective warning.

Q. Have you assessed this warning section in here and whether or not that related to your opinion?

A. Yes.

Q. Okay. And before I get to that, have you also evaluated any new label for Sulindac beyond this one what we're looking at?

A. Yes.

* * *

* * *

Q. Strike that. This says two things here. It says, quote, stop your NSAID and call your healthcare provider. Is that correct?

A. That's correct.

Q. How does that relate to the fact that it's putting information in a patient's hands that they don't even talk to their doctor first. They are telling them you have to stop the medication and to call their doctor. What relevance, if any, is that to your opinion?

A. If you keep taking the medication, for example, if you call your doctor but continued taking the medication because you had a prescription for it, you're adding more drug there which can make the condition get actually worse. They're saying stop the medication, call your doctor so there's no more exposure.

Q. And does this medication guide for Sulindac also list a number of other NSAIDS on the market?

A. It does.

Q. Approximately—you don't have to count—how many.

A. There's probably 10 to 14 I think there, I believe.

Q. Okay. And you mentioned that there is an order to create this new label. Is that correct, sir?

A. Correct.

Q. Who did that order come from?

A. The Food and Drug Administration.

Q. What if any bearing—did this order come from just Sulindac or for other NSAIDS as well?

A. It was for all nonsteroidal anti-inflammatory drugs.

Q. The fact it was for all NSAIDS, what if any bearing does that have on your opinion about the effectiveness or lack thereof of the prior Sulindac label?

A. Well, it definitely indicates the label was inadequate.

Q. As well as for the other NSAIDS?

A. Yes.

Q. Let's address the warning section of the prior label, sir, and I direct you to a section called hypersensitivity. Tell us what it's talking about generally, first of all, before we go into specifics.

A. This is basically talking about hypersensitivity reaction which when you talk about hypersensitivity it's just a, seems to be an excessive response, but in my reading of this label it basically describes hypersensitivity that primarily describes liver dysfunction.

Q. And why do you say that, that it primarily describes liver dysfunction?

A. Well, it starts off again, and remember, you want the more serious things at the front, and so if you just look under hypersensitivity it starts off including abnormalities in one or more liver function tests. These are laboratory tests that assess whether your liver is undergoing damage. And then it mentions severe skin reactions that occurred during therapy. And it also talks about unexplained fever, rash, constitutional symptoms which could be other organ effects, and it also has elevated temperature.

Again, it talks about abnormalities in liver function. And so this primarily talks about liver dysfunction that is caused by the drug.

* * *

* * *

THE COURT: Take a different tack at it. If he still objects, we will approach.

MR. THOMAS: Oh, I'm sorry, but it is the substance, it is an undisclosed substance.

THE COURT: Okay. That's the grounds?

MR. THOMAS: Yes.

THE COURT: Okay. That's the grounds?

MR. THOMAS: Yes.

THE COURT: Understood. Proceed.

Q. BY MR. JENSEN: How does this statement about hypersensitivity in relation to liver relate to the efficacy or the adequacy of a label?

THE COURT: No. No. We will cover that at the—we will cover that at the break.

Q. Okay. Have you reached a conclusion as to whether the SJS and TEN warning in the warning section of the new label is better than the fact that there is no SJS and TEN warning in the old label.

A. Yes.

Q. What is it?

A. It is better.

Q. Have you reached a conclusion as to whether the new label is better by having a medication guide in it?

A. Absolutely, yes.

Q. Have you reached—

THE COURT: You've really got to stop leading. You've got to ask open-ended questions.

Q. What, if any, opinion have you reached as to whether or not the old label had an effective warning for SJS and TEN?

A. As I've said before, I do not think it was effective. The new label basically has a better warning. It's clearer and the presence of a medication guide makes it even better with regard to giving information to the patient as well as to the doctor that may be reading the label.

THE COURT: All right, you want to get into that area. You were trying to approach, so it's probably a good time for a break so we don't waste the jury's time while we argue about that. Let's take the afternoon break.